



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Meloxicam; Nicarbazin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during October 2012. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect original and supplemental approval actions during October 2012, as listed in table 1 of this document. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the Center for Veterinary Medicine FOIA Electronic Reading Room:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During October 2012

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
009-476	Phibro Animal Health Corp., GlenPointe Centre East, Third floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666	NICARB 25% (nicarbazin) Type A medicated article	Supplement revising nicarbazin dosage to a range consistent with dosage approved for use in combination feeds.	558.366	No	CE <sup>1</sup>
098-378	Phibro Animal Health Corp., GlenPointe Centre East, Third floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666	NICARB 25% (nicarbazin) and bacitracin methylene disalicylate Type A medicated articles	Supplement revising nicarbazin dosage to a range consistent with dosage approved for use in combination feeds.	558.366	No	CE <sup>1</sup>
200-496	Cross Vetpharm Group	AMPROMED P for	Original approval as a	520.100	Yes	CE <sup>1</sup>

<sup>1</sup> The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

	Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland	Poultry (amprolium) 9.6% Oral Solution	generic copy of NADA 13-149.			
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This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects

#### 21 CFR Part 520

Animal drugs.

#### 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 558 are amended as follows:

#### PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. In § 520.100, revise paragraph (b)(4) and the introductory text in paragraph (d)(1) to read as follows:

#### § 520.100 Amprolium.

\* \* \* \* \*

(b) \* \* \*

(4) No. 061623 for use of products described in paragraphs (a)(1) and (a)(2) of this section as in paragraph (d) of this section.

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(d) \* \* \* (1) Growing chickens, turkeys, and laying hens. It is used in drinking water as follows:

\* \* \* \* \*

#### PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

4. In § 558.366, in paragraph (d), amend the table as follows:

a. Revise the entries for “90.8 to 181.6 (0.01 to 0.02 pct)”.

b. In the entry for “113.5 (0.0125 pct)”, in the entry for “Chickens; aid in preventing outbreaks of cecal (Eimeria tenella) and intestinal (E. acervulina, E. maxima, E. necatrix, and E. brunetti) coccidiosis”, remove “066104” from the “Sponsor” column.

c. In the entry for “113.5 (0.0125 pct)”, in the entry for “Bacitracin methylene disalicylate 30”, remove “066104” from the “Sponsor” column.

The revisions read as follows:

§ 558.366 Nicarbazin.

\* \* \* \* \*

(d) \* \* \*

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
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90.8 to 181.6 (0.01 to 0.02 pct)		Broiler chickens: As an aid in preventing outbreaks of cecal ( <u>Eimeria tenella</u> ) and intestinal ( <u>E. acervulina</u> , <u>E. maxima</u> , <u>E. necatrix</u> , and <u>E. brunetti</u> ) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton.	066104
	Bacitracin methylene disalicylate 4 to 50 and roxarsone 22.7 to 45.4.	Broiler chickens: As an aid in preventing outbreaks of cecal ( <u>Eimeria tenella</u> ) and intestinal ( <u>E. acervulina</u> , <u>E. maxima</u> , <u>E. necatrix</u> , and <u>E. brunetti</u> ) coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Discontinue medication 5 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Do not feed to laying hens in production. Nicarbazin as provided by No. 066104; bacitracin methylene disalicylate and roxarsone by No. 046573 in § 510.600(c) of this chapter.	066104
	Bacitracin methylene disalicylate 30.	Broiler chickens: As an aid in preventing outbreaks of cecal ( <u>Eimeria tenella</u> ) and intestinal ( <u>E. acervulina</u> , <u>E. maxima</u> , <u>E. necatrix</u> , and <u>E. brunetti</u> ) coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton.	066104
	Penicillin 2.4 to 50	Broiler chickens: As an aid in preventing outbreaks of cecal ( <u>Eimeria tenella</u> ) and intestinal ( <u>E. acervulina</u> , <u>E. maxima</u> , <u>E. necatrix</u> , and <u>E. brunetti</u> ) coccidiosis, and for increased rate of weight gain and improved feed	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Do not use in flushing mashers. Do not feed to chickens producing eggs for human consumption. Discontinue medication 5 days	066104

		efficiency.	before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Penicillin as procaine penicillin G. Nicarbazin and penicillin as provided by No. 066104 in § 510.600(c) of this chapter.	
	Penicillin 2.4 to 50 and roxarsone 22.7 to 45.4	Broiler chickens: As an aid in preventing outbreaks of cecal ( <u>Eimeria tenella</u> ) and intestinal ( <u>E. acervulina</u> , <u>E. maxima</u> , <u>E. necatrix</u> , and <u>E. brunetti</u> ) coccidiosis, and for increased rate of weight gain and improved feed efficiency, and improved pigmentation.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Feed as the sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; do not use in flushing mashers. Discontinue medication 5 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Do not feed to laying hens in production. Penicillin as procaine penicillin G. Nicarbazin and penicillin as provided by No. 066104; roxarsone by No. 046573 in § 510.600(c) of this chapter.	066104
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Dated: December 21, 2012

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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